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EXAMINER RAJ, RAJIV J				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/509,510

**Applicant(s)**

WATANABE ET AL.

**Examiner**

RAJIV J. RAJ

**Art Unit**

4143

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-31 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 28 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-85/86)  
Paper No(s)/Mail Date 28 September 2004  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of Claims**

1. This action is in reply to the application filed on 28 September 2004.
2. Claims 1-31 are currently pending and have been examined.

### ***Information Disclosure Statement***

3. The Information Disclosure Statement filed 28 September 2004 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

### **Priority**

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

### **Claim Rejections - 35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 4143

7. Claims 1-3, 6-14, and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington et al.(US 5822715) (hereinafter Worthington) in view of Allen, III (US 4731726) (hereinafter Allen).

**Claim 1**

**Worthington as shown, discloses the following limitations:**

- *a notifying unit operable to notify the user of the dosage calculated by the dosage calculating unit (see at least Worthington Fig.2 Item10,54 and Column: 6 Lines: 13-23 "Display 14 is also designed to display the predicted future blood glucose values in graphical form. Display 14 preferably displays a graph 48 which includes a blood glucose value curve 50 generated from the predicted blood glucose values. Graph 48 also includes a hypoglycemic line 52 indicating a hypoglycemic threshold of the patient and a hyperglycemic line 53 indicating a hyperglycemic threshold of the patient. Apparatus 10 also includes an audio transducer, such as a speaker 54, for audibly alerting the patient when a predicted future blood glucose value lies below the hypoglycemic threshold.")*

Worthington does not disclose the following limitations, however Allen, as shown, does:

- *a measuring unit operable to measure biological information obtained from one of inside and surface of a user's body; (see at least Allen Fig:5B Items:222-230)*
- *a dosage calculating unit operable to calculate a dosage on the basis of the biological information; (see at least Allen Fig.8A, Column:18 Lines:65-68, and Column:19 Lines:1-15 "Steps 440-448 calculate the supplemental dosage according to either of two methods. Step 440 will first determine which method is prescribed by the physician for this particular patient. The first method (A), steps 442-446, calculates the supplement based on 50 mg/dl increments in the current blood sugar over the minimum blood sugar for a supplement. In step 442, a temporary variable TMP-BS is set equal to this minimum, generally 200 mg/dl. The supplement value (SUPP) is set to zero. Step 446 tests the current blood sugar (BS) against the variable TMP-BS and TMP-BS against the minimum blood sugar for a supplement plus 200. If either the current blood sugar (BS) is less than TMP-BS or TMP-BS is*

greater than 200 plus the minimum blood sugar, then the calculation of the supplement is complete. If not, then in step 446, TMP-BS is increased by 50 and SUPP is increased by 1. Thus, for each increment of 50 mg/dl in the current blood sugar over the minimum, SUPP will be increased by one unit. The alternate method of calculating the supplement (B) shown in step 448 uses a prescribed percentage of the current R insulin base. The current R base is defined as the most recently scheduled base dose of R-type insulin. SUPP is determined by taking the prescribed percentage of the current R base and rounding it off to the nearest unit, but in no event less than one unit.")

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the a *notifying unit operable to notify the user of the dosage calculated by the dosage calculating unit*, as taught by Worthington, with a *measuring unit operable to measure biological information obtained from one of inside and surface of a user's body* and a *dosage calculating unit operable to calculate a dosage on the basis of the biological information*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

## Claim 2

The combination of Worthington/Allen disclose all of the limitations of claim 1. Allen further discloses the following limitations:

- *a correspondence memory operable to memorize a correspondence between the biological information and the dosage; (see at least Allen Column:30 Lines:3-5 "and communication linkage means for at said times establishing a communication linkage between said computer means and said monitor means.")*
- *a calculating unit operable to calculate the dosage corresponding to the biological information, with reference to the correspondence. (see at least Allen Fig:8A Column:18 Lines:65-68, and Column:19 Lines:1-15)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught in Claim 1, as taught by Worthington/Allen, with a *correspondence memory operable to*

*memorize a correspondence between the biological information and the dosage and a calculating unit operable to calculate the dosage corresponding to the biological information, with reference to the correspondence, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)*

**Claim 3**

The combination of Worthington/Allen disclose all of the limitations of claim 2. Worthington further discloses the following limitation:

- *a correspondence rewriting unit operable to receive an external input via the communication controlling unit and to rewrite contents of the correspondence stored in the correspondence memory on the basis of the external input; (see at least Worthington Fig:2 Items:10-36)*

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a communication controlling unit, which is connected to an external terminal via a network, operable to control a communication with the external terminal. (see at least Allen Fig:4 Items:100-114)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught above with *a communication controlling unit, which is connected to an external terminal via a network, operable to control a communication with the external terminal*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

**Claim 6**

The combination of Worthington/Allen disclose all of the limitations of claim 2. Worthington further discloses the following limitation:

- *a correspondence rewriting unit operable to receive an external input via the data inputting unit and to rewrite contents of the correspondence stored in the correspondence memory on the basis of the external input; (see at least Worthington Fig:2 Items:10-36)*

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a data inputting unit operable to receive an input of data from the user.* (see at least Allen Fig:2 Items:150 Fig:4 Items:100-112)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught above, as disclosed in Worthington/Allen, with *a data inputting unit operable to receive an input of data from the user*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

#### Claim 7

The combination of Worthington/Allen disclose all of the limitations of claim 1. Worthington further discloses the following limitation:

- *a dosage memory operable to memorize the dosage;* (see at least Worthington Column:6 Lines:60-62 "Memory 24 also stores blood glucose values of the patient, the insulin dose values, the insulin types")
- *a dosage storing unit operable to store the calculated dosage together with a calculation time of day into the dosage memory* (see at least Worthington Column:6 Lines:60-64 "Memory 24 also stores blood glucose values of the patient, the insulin dose values, the insulin types, and the parameter values used by microprocessor 22 to calculate future blood glucose values, supplemental insulin doses, and carbohydrate supplements. Each blood glucose value and insulin dose value is stored in memory 24 with a corresponding date and time. Memory 24 is preferably a non-volatile memory, such as an electrically erasable read only memory")

#### Claim 8

The combination of Worthington/Allen disclose all of the limitations of claim 1. Worthington further discloses the following limitation:

- *a biological information memory operable to memorize the biological information;* (see at least Worthington Column:6 Lines:60-62)

- *a biological information storing unit operable to store the biological information measured by the measuring unit together with a measurement time of day into the biological information memory* (see at least Worthington Column:6 Lines:60-64)

**Claim 9**

The combination of Worthington/Allen disclose all of the limitations of claim 1. Worthington further discloses the following limitation:

- *a physical condition memory operable to memorize the physical condition of the user;* (see at least Worthington Column:6 Lines:60-62)
- *a physical condition storing unit operable to store the physical condition of the user together with a measurement time of day into the physical condition memory* (see at least Worthington Column:6 Lines:60-64)

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a physical condition measuring unit operable to measure a physical condition of the user* (see at least Allen Fig:5B Items:222-230)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught above, as disclosed in Worthington/Allen, with *a physical condition measuring unit operable to measure a physical condition of the user*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

**Claim 10**

The combination of Worthington/Allen disclose all of the limitations of claim 1. Worthington further discloses the following limitations:

- *a dosage memory operable to memorize the dosage;* (see at least Worthington Column:6 Lines:60-62)
- *a dosage storing unit operable to store the calculated dosage together with a calculation time of day into the dosage memory* (see at least Worthington Column:6 Lines:60-64)



- *a communication controlling unit, which is connected to an external terminal via a network, (see at least Worthington Fig:2 Items:22,24, & 32-36)*
- *operable to output the dosage and the calculation time of day stored in the dosage memory to the external terminal via the network. (see at least Worthington Column:6 Lines:60-64 Fig:2 Items:22,24, & 32-36)*

**Claim 11**

The combination of Worthington/Allen disclose all of the limitations of claim 1. Worthington further discloses the following limitations:

- *a biological information memory operable to memorize the biological information; (see at least Worthington Column:6 Lines:60-62)*
- *a biological information storing unit operable to store the biological information measured by the measuring unit together with a measurement time of day into the biological information memory (see at least Worthington Column:6 Lines:60-64)*
- *a communication controlling unit, which is connected to an external terminal via a network, (see at least Worthington Fig:2 Items:22,24, & 32-36)*
- *operable to output the biological information and the measurement time of day stored in the biological information memory to the external terminal via the network (see at least Worthington Column:6 Lines:60-64 Fig:2 Items:22,24, & 32-36)*

**Claim 12**

The combination of Worthington/Allen disclose all of the limitations of claim 1. Worthington further discloses the following limitation:

- *a physical condition memory operable to memorize a physical condition of the user; (see at least Worthington Column:6 Lines:60-62)*
- *a physical condition storing unit operable to store the physical condition of the user together with a measurement time of day into the physical condition memory (see at least Worthington Column:6 Lines:60-64)*

- *a communication controlling unit, which is connected to an external terminal via a network, (see at least Worthington Fig:2 Items:22,24, & 32-36)*
- *operable to output the physical condition of the user and the measurement time of day stored in the physical condition memory to the external terminal via the network (see at least Worthington Column:6 Lines:60-64 Fig:2 Items:22,24, & 32-36)*

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a physical condition measuring unit operable to measure a physical condition of the user (see at least Allen Fig:5B Items:222-230)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught above, as disclosed in Worthington/Allen, with a *physical condition measuring unit operable to measure a physical condition of the user*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

#### **Claim 13**

##### **Worthington as shown, discloses the following limitations:**

- *an injecting unit operable to inject the dosage of a medicine calculated by the dosage calculating unit (see at least Worthington Column:13 Lines:24-30 "Microprocessor 22 calculates insulin action value  $F_{sub.k}(t_{sub.j})$  for the dose from equation (2A) as: #EQU3# Microprocessor 22 thus determines that the regular insulin dose injected")*

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a measuring unit operable to measure biological information obtained from one of inside or surface of a user's body (see at least Allen Fig:5B Items:222-230)*
- *a dosage calculating unit operable to calculate a dosage on the basis of the biological information; (see at least Allen Fig.8A, Column:18 Lines:65-68, and Column:19 Lines:1-15)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught above, as disclosed in Worthington/Allen, with a *measuring unit operable to measure biological information obtained from one of inside or surface of a user's body and a dosage calculating unit*

Art Unit: 4143

*operable to calculate a dosage on the basis of the biological information, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)*

**Claim 14**

The combination of Worthington/Allen disclose all of the limitations of claim 13. Allen further discloses the following limitations:

- *a correspondence memory operable to memorize a correspondence between the biological information and the dosage; (see at least Allen Column:30 Lines:3-5)*
- *a calculating unit operable to calculate the dosage corresponding to the biological information, with reference to the correspondence. (see at least Allen Fig:8A Column:18 Lines:65-68, and Column:19 Lines:1-15)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught in Claim 13, as taught by Worthington/Allen, with *a correspondence memory operable to memorize a correspondence between the biological information and the dosage and a calculating unit operable to calculate the dosage corresponding to the biological information, with reference to the correspondence*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

**Claim 23**

The combination of Worthington/Allen disclose all of the limitations of claim 14. Worthington further discloses the following limitation:

- *a correspondence rewriting unit operable to receive an external input via the communication controlling unit and to rewrite contents of the correspondence stored in the correspondence memory on the basis of the external input. (see at least Worthington Fig:2 Items:10-36)*

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a communication controlling unit, which is connected to an external terminal via a network, operable to communicate with the external terminal;* (see at least Allen Fig.4 Items:100-114)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught in Claim 14, as taught by Worthington/Allen, with *a communication controlling unit, which is connected to an external terminal via a network, operable to communicate with the external terminal*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

#### **Claim 24**

The combination of Worthington/Allen disclose all of the limitations of claim 14. Worthington further discloses the following limitation:

- *a correspondence rewriting unit operable to receive an external input via the data inputting unit and to rewrite contents of the correspondence stored in the correspondence memory on the basis of the external input;* (see at least Worthington Fig:2 Items:10-36)

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a data inputting unit operable to receive an input of data from the user.* (see at least Allen Fig:2 Items:150 Fig:4 Items:100-112)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught above, as disclosed in Worthington/Allen, with *a data inputting unit operable to receive an input of data from the user*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

#### **Claim 25**

The combination of Worthington/Allen disclose all of the limitations of claim 14. Worthington further discloses the following limitation:

- *a biological information memory operable to memorize the biological information;*  
(see at least Worthington Column:6 Lines:60-62)

- *a biological information storing unit operable to store the biological information measured by the measuring unit together with a measurement time of day into the biological information memory (see at least Worthington Column:6 Lines:60-64)*

**Claim 26**

The combination of Worthington/Allen disclose all of the limitations of claim 14. Worthington further discloses the following limitations:

- *a biological information memory operable to memorize the biological information; (see at least Worthington Column:6 Lines:60-62)*
- *a biological information storing unit operable to store the biological information measured by the measuring unit together with a measurement time of day into the biological information memory (see at least Worthington Column:6 Lines:60-64)*
- *a communication controlling unit, which is connected to an external terminal via a network, (see at least Worthington Fig:2 Items:22,24, & 32-36)*
- *operable to output the biological information and the measurement time of day stored in the biological information memory to the external terminal via the network (see at least Worthington Column:6 Lines:60-64 Fig:2 Items:22,24, & 32-36)*

**Claim 27**

**Worthington as shown, discloses the following limitations:**

- *a dosage determination supporting apparatus operable to support a determination of a dosage to be administered to the user, (see at least Worthington Fig:2 Items:10)*
- *a server apparatus, which is connected to the dosage determination supporting apparatus via a network, operable to send the correspondence to the dosage determination supporting apparatus (see at least Worthington Fig:2 Items:22, 32-36 Fig:3 Item:40))*
- *a notifying unit operable to notify the user of the dosage calculated by the calculating unit; (see at least Worthington Fig.2 Item10,54 and Column: 6 Lines: 13-23)*

- *a correspondence rewriting unit operable to rewrite the correspondence that is received from the server apparatus and stored in the correspondence memory (see at least Worthington Fig:2 Items:10-36)*

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *with reference to a correspondence between biological information obtained from one of inside or surface of the user's body and the dosage of a medicine; (see at least Allen Fig:5B Items:222-230)*
- *a measuring unit operable to measure the biological information of the user; (see at least Allen Fig:5B Items:222-230)*
- *a correspondence memory operable to memorize the correspondence; (see at least Worthington Column:30 Lines:3-5)*
- *a calculating unit operable to calculate the dosage corresponding to the biological information, with reference to the correspondence; (see at least Allen Fig:8A Column:18 Lines:65-68, and Column:19 Lines:1-15)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine a dosage determination supporting apparatus operable to support a determination of a dosage to be administered to the user, a server apparatus, which is connected to the dosage determination supporting apparatus via a network, operable to send the correspondence to the dosage determination supporting apparatus, a notifying unit operable to notify the user of the dosage calculated by the calculating unit, and a correspondence rewriting unit operable to rewrite the correspondence that is received from the server apparatus and stored in the correspondence memory, as taught by Worthington, with a *with reference to a correspondence between biological information obtained from one of inside or surface of the user's body and the dosage of a medicine, a measuring unit operable to measure the biological information of the user, a correspondence memory operable to memorize the correspondence and a calculating unit operable to calculate the dosage corresponding to the biological information, with reference to the correspondence*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

**Claim 28**

**Worthington as shown, discloses the following limitations:**

- *a unit operable to receive the biological information from the dosage determination supporting apparatus; (see at least Worthington Fig:3 Items:10,38,40 & Fig:4)*
- *a calculating unit operable to calculate the dosage corresponding to the received biological information, with reference to the correspondence memory (see at least Worthington Fig:2 Items:10-24)*
- *a unit operable to send the dosage calculated by the calculating unit to the dosage determination supporting apparatus (see at least Worthington Fig:3 Items: 10,38,40)*

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a correspondence memory operable to memorize a correspondence between biological information obtained from one of inside and surface of the user's body and the dosage; (see at least Allen Column:30 Lines:3-5)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine a *unit operable to receive the biological information from the dosage determination supporting apparatus, a calculating unit operable to calculate the dosage corresponding to the received biological information, with reference to the correspondence memory, and a unit operable to send the dosage calculated by the calculating unit to the dosage determination supporting apparatus*, as taught by Worthington, with a *correspondence memory operable to memorize a correspondence between biological information obtained from one of inside and surface of the user's body and the dosage*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

8. Claims 15-22, are rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington in view of Allen, in further view of Ellinwood, Jr. (US 4146029) (hereinafter Ellinwood).

**Claim 15**

The combination of Worthington/Allen disclose all of the limitations of claim 14. Worthington further discloses the following limitations:

- *a setting unit operable to set an amount of the medicine to be discharged by the piston; (see at least Worthington Column:4 Lines:10-15 "The apparatus also includes a user interface for entering in the apparatus an insulin dose value l.sub.k representative of an insulin dose administered to the patient prior to time t.sub.d. The apparatus further includes a memory for storing maximum and minimum values defining a target blood glucose range of the patient.")*
- *an adjusting unit operable to adjust the amount of the medicine to be discharged that is set by the setting unit so that the dosage of the medicine calculated by the calculating unit may be administered. (see at least Worthington Column:16 Lines:12-18 "The patient takes the supplemental insulin dose and records the dose value in apparatus 10. From taking the supplemental insulin dose, the patient obtains eight hours of normal blood glucose in place of hyperglycemia. An adjusted insulin sensitivity may also be determined from the dose values and measured blood glucose values recorded in apparatus 10 as follows.")*

Worthington/Allen does not disclose the following limitations, however Ellinwood, as shown, does:

- *an injection needle; (see at least Ellinwood Fig:18 &19)*
- *a medicine containing unit operable to contain the medicine; (see at least Ellinwood Fig:11 Items:152 and related text)*
- *a piston operable to discharge the medicine contained in the medicine containing unit into the injection needle; (see at least Ellinwood Fig:11 Items:191,192 and related text)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught above, as disclosed in Worthington/Allen, with *an injection needle, a medicine containing unit operable to contain the medicine, and a piston operable to discharge the medicine contained in the medicine containing unit into the injection needle*, as taught by Allen, with the motivation of providing a more



Art Unit: 4143

effective and efficient medication program responsive to a patient's needs at the current time. (see at least Ellinwood Column:1 Lines:19-21)

**Claim 16**

The combination of Worthington/Allen/Ellinwood disclose all of the limitations of claim 15. Worthington further discloses the following limitations:

- *a notifying unit operable to notify the user of the dosage calculated by the dosage calculating unit* (see at least Worthington Fig.2 Item10,54 and Column: 6 Lines: 13-23)

**Claim 17**

The combination of Worthington/Allen/Ellinwood disclose all of the limitations of claim 16. Worthington further discloses the following limitations:

- *a user verification unit operable to have the user verify the dosage calculated by the calculating unit and to stop a discharge of the medicine when a verification is not obtained from the user* (see at least Worthington Column: 4 Lines: 29-39 "The processor is also programmed to determine a corrective action for the patient when the future blood glucose value  $G(t.sub.j)$  lies outside of the target range. The corrective action is preferably an administration of a supplemental insulin dose when the future blood glucose value  $G(t.sub.j)$  lies above the target range or a consumption of a number of grams of carbohydrates when the future blood glucose value  $G(t.sub.j)$  lies below the target range. The processor is programmed to determine the supplemental insulin dose in dependence upon the insulin sensitivity value")

**Claim 18**

The combination of Worthington/Allen/Ellinwood disclose all of the limitations of claim 15. Worthington further discloses the following limitations:

- *a correcting unit operable to correct the amount of the medicine to be discharged that is set by the setting unit* (see at least Worthington Column: 4 Lines: 33-41)

Art Unit: 4143

**Claim 19**

The combination of Worthington/Allen/Ellinwood disclose all of the limitations of claim 18.

Worthington further discloses the following limitation:

- *a dosage memory operable to memorize the dosage; (see at least Worthington Column:6 Lines:60-62)*
- *a dosage storing unit operable to store the dosage of the medicine having been administered to the user through the injecting unit together with an administration time of day into the dosage storing memory (see at least Worthington Column:6 Lines:60-64)*

**Claim 20**

The combination of Worthington/Allen/Ellinwood disclose all of the limitations of claim 15.

Worthington further discloses the following limitation:

- *a dosage tolerance limits memory operable to memorize tolerance limits of the dosage (see at least Worthington Column:23 Lines:10-16 "storing in said memory an insulin sensitivity value representative of an insulin sensitivity of the patient, information for determining an insulin action value  $F_{sub.k}(t_{sub.d})$  representative of a fraction of insulin action remaining at time  $t_{sub.d}$  from said insulin dose, and maximum and minimum values defining a target blood glucose range of the patient;")*
- *a discharged amount checking unit operable to check whether the amount of the medicine to be discharged is within the tolerance limits. (see at least Worthington Column:10 Lines:16-19, 28-29 "Apparatus 10 is used by the patient to predict a future blood glucose value and to generate a corrective action when the predicted value lies outside of the patient's target blood glucose range . . . entering and storing dose value  $I_{sub.k}$  and insulin type")*

**Claim 21**

The combination of Worthington/Allen/Ellinwood disclose all of the limitations of claim 20.

Worthington further discloses the following limitation:

- *a warning unit operable to warn the user when the amount of the medicine to be discharged is judged to be beyond the tolerance limits. (see at least Worthington Column:6 Lines:20-23 "Apparatus 10 also includes an audio transducer, such as a speaker 54, for audibly alerting the patient when a predicted future blood glucose value lies below the hypoglycemic threshold.")*

**Claim 22**

The combination of Worthington/Allen/Ellinwood disclose all of the limitations of claim 15.

Worthington further discloses the following limitation:

- *a dosage memory operable to memorize the dosage; (see at least Worthington Column:6 Lines:60-62)*
- *a dosage storing unit operable to store the dosage of the medicine having been administered to the user through the injecting unit together with an administration time of day into the dosage storing memory (see at least Worthington Column:6 Lines:60-64)*
- *a correspondence rewriting unit operable to receive an external input via the communication controlling unit and to rewrite contents of the correspondence stored in the correspondence memory on the basis of the external input; (see at least Worthington Fig:2 Items:10-36)*

Worthington does not disclose the following limitation, however Allen, as shown, does:

- *a communication controlling unit, which is connected to an external terminal via a network, operable to control a communication with the external terminal. (see at least Allen Fig:4 Items:100-114)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught above, as taught in Worthington/Allen/Ellinwood, with *a communication controlling unit, which is connected to an external terminal via a network, operable to control a communication with the external terminal*, as taught by Allen, with the motivation of administering more accurately and effective doses of medication based on a patient's current condition. (see at least Allen Column:2 Lines:1-4)

9. Claims 4,5, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worthington in view of Allen, in further view of Iliff (US 6234964 B1) (hereinafter Iliff).

**Claim 4**

The combination of Worthington/Allen disclose all of the limitations of claim 3. Iliff further discloses the following limitations:

- *an external input authenticating unit operable to authenticate a person who inputs the external input, (see at least Iliff Fig:3 Items:200)*
- *wherein the correspondence rewriting unit rewrites the contents of the correspondence stored in the correspondence memory on the basis of the external input only when the person is approved. (see at least Iliff Fig:3 Items:200)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught in Worthington/Allen, with *an external input authenticating unit operable to authenticate a person who inputs the external input and wherein the correspondence rewriting unit rewrites the contents of the correspondence stored in the correspondence memory on the basis of the external input only when the person is approved*, as taught by Iliff, with the motivation of more accurately monitoring patient's present condition so as to more effectively administer the proper dose of medication (see at least Iliff Column:2 Lines:45-49)

**Claim 5**

The combination of Worthington/Allen/Iliff disclose all of the limitations of claim 4. Iliff further discloses the following limitations:

- *the external input authenticating unit performs an authentication on the basis of a physical characteristic of the person, (see at least Iliff Fig:3 Items:200-202)*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught in Worthington/Allen, with *the external input authenticating unit performs an authentication on the basis of a physical characteristic of the person*, as taught by Iliff, with the motivation of more accurately

Art Unit: 4143

monitoring patient's present condition so as to more effectively administer the proper dose of medication (see at least Iliff Column:2 Lines:45-49)

**Claim 29**

**Worthington as shown, discloses the following limitations:**

- *sends/receives various kinds of data to/from the dosage determination supporting apparatus* (see at least Worthington Fig:2 Items:10, 32-38)

Worthington does not disclose the following limitation, however Iliff, as shown, does:

- *a judging unit operable to judge, with reference to the correspondence memory, whether the dosage corresponding to the received biological information can be authenticated* (see at least Iliff Fig:3 Items:200,202,220)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the limitations taught in Worthington/Allen, with *a judging unit operable to judge, with reference to the correspondence memory, whether the dosage corresponding to the received biological information can be authenticated*, as taught by Iliff, with the motivation of more accurately monitoring patient's present condition so as to more effectively administer the proper dose of medication (see at least Iliff Column:2 Lines:45-49)

**Claim 30**

**Worthington as shown, discloses the following limitations:**

- *a step in which the terminal apparatus affixes a signature to the historical data regarding a health condition of the user, using a private key of the user;* (see at least Worthington Fig:2 Items:22,24,32-38 Column:10 Lines: 55-57 "microprocessor 22 by glucose meter 28, coded and labeled with the date and time of the measurement, and stored in memory 24.")
- *a step in which the terminal apparatus sends the historical data having the affixed signature to the server apparatus;* (see at least Worthington Column:7 Lines: 16-23 "Apparatus 10 further includes an input/output port 34, preferably a serial port, which is connected to microprocessor 22. Port 34 is connected to a modem 32 by an interface, preferably a standard RS232 interface. Modem 32 is for establishing a

communication link between apparatus 10 and a healthcare provider computer 38 through a communication network 36. Modem 32 is capable of transmitting data to and receiving data from provider computer 38")

- *a step in which the server apparatus receives the historical data having the affixed signature; (see at least Worthington Column:7 Lines: 38-43 "Healthcare provider computer 38 is designed to receive the patient's blood glucose values and insulin dose values from apparatus 10 and calculate from the values an adjusted insulin sensitivity value for the patient, as will be explained in the operation section below. ")*

Worthington does not disclose the following limitation, however Iliff, as shown, does:

- *a step in which the server apparatus verifies the signature affixed to the historical data, using a registered public key of the user (see at least Iliff Column:9 Lines: 58-60 "If so, the system 100 verifies the patient's identification and retrieves their medical record at the patient login process 200")*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine *a step in which the terminal apparatus affixes a signature to the historical data regarding a health condition of the user, using a private key of the user, a step in which the terminal apparatus sends the historical data having the affixed signature to the server apparatus, and a step in which the server apparatus receives the historical data having the affixed signature*, as taught in Worthington, with *a step in which the server apparatus verifies the signature affixed to the historical data, using a registered public key of the user*, as taught by Iliff, with the motivation of more accurately monitoring patient's present condition so as to more effectively administer the proper dose of medication (see at least Iliff Column:2 Lines:45-49)

#### **Claim 31**

**Worthington as shown, discloses the following limitations:**

- *a step in which the terminal apparatus affixes a signature to the historical data regarding a health condition of the user, using a private key of the user; (see at least Worthington Fig:2 Items:22,24,32-38 Column:10 Lines: 55-57 )*

- *a step in which the terminal apparatus sends the historical data having the affixed signature to the server apparatus;* (see at least Worthington Column:7 Lines: 16-23)
- *a step in which the server apparatus receives the historical data having the affixed signature;* (see at least Worthington Column:7 Lines: 38-43)

Worthington does not disclose the following limitation, however Iliff, as shown, does:

- *a step in which the server apparatus verifies the signature affixed to the historical data, using a registered public key of the user* (see at least Iliff Column:9 Lines: 58-60)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine *a step in which the terminal apparatus affixes a signature to the historical data regarding a health condition of the user, using a private key of the user, a step in which the terminal apparatus sends the historical data having the affixed signature to the server apparatus, and a step in which the server apparatus receives the historical data having the affixed signature*, as taught in Worthington, with *a step in which the server apparatus verifies the signature affixed to the historical data, using a registered public key of the user*, as taught by Iliff, with the motivation of more accurately monitoring patient's present condition so as to more effectively administer the proper dose of medication (see at least Iliff Column:2 Lines:45-49)

Art Unit: 4143

### **Conclusion**

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **Rajiv J. Raj** whose telephone number is **571-270-3930**. The Examiner can normally be reached on Monday-Friday, 7:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **James A. Reagan** can be reached at **571.272.6710**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair> <<http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

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/Rajiv J Raj/ Patent Examiner Art Unit 4143

/James A. Reagan/Supervisory Patent Examiner, Art Unit 4143